

#### **§ 493.1219**

493.1256, § 493.1271, and §§ 493.1281 through 493.1299.

#### **§ 493.1219 Condition: Histopathology.**

If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1273, and §§ 493.1281 through 493.1299.

#### **§ 493.1220 Condition: Oral pathology.**

If the laboratory provides services in the subspecialty of Oral pathology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, and §§ 493.1281 through 493.1299.

#### **§ 493.1221 Condition: Cytology.**

If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1274, and §§ 493.1281 through 493.1299.

#### **§ 493.1225 Condition: Clinical cytogenetics.**

If the laboratory provides services in the specialty of Clinical cytogenetics, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1276, and §§ 493.1281 through 493.1299.

#### **§ 493.1226 Condition: Radiobioassay.**

If the laboratory provides services in the specialty of Radiobioassay, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, and §§ 493.1281 through 493.1299.

#### **§ 493.1227 Condition: Histocompatibility.**

If the laboratory provides services in the specialty of Histocompatibility, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1278, and §§ 493.1281 through 493.1299.

#### **GENERAL LABORATORY SYSTEMS**

#### **§ 493.1230 Condition: General laboratory systems.**

Each laboratory that performs non-waived testing must meet the applicable general laboratory systems requirements in §§ 493.1231 through 493.1236, un-

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less HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems as specified in § 493.1239 for each specialty and subspecialty of testing performed.

#### **§ 493.1231 Standard: Confidentiality of patient information.**

The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control.

#### **§ 493.1232 Standard: Specimen identification and integrity.**

The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

#### **§ 493.1233 Standard: Complaint investigations.**

The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.

#### **§ 493.1234 Standard: Communications.**

The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

#### **§ 493.1235 Standard: Personnel competency assessment policies.**

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.